Remarks

This is in response to the Official Action of June 14, 2006.

The indication of allowability of claims 1, 3-5, 7-10 and 25-26 is acknowledged with appreciation.

Objections.

Claims 17-20, 21 and 24 stand objected to in paragraphs 5-7 of the Official Action. These claims have been cancelled to simplify the issues, and it is accordingly submitted that this rejection may be withdrawn.

Rejection under 35 U.S.C. § 112, first paragraph, enablement.

Claims 21-24 stand rejected as lacking enablement in paragraphs 8-9 of the Official Action. These claims have been cancelled as noted above, and it is respectfully submitted that this rejection may be withdrawn.

Rejection under 35 U.S.C. § 112, first paragraph, written description.

Claims 6 and 21-24 stand rejected as lacking written description in paragraph 10 of the Official Action. Claims 21-24 have been cancelled. Reconsideration as to claim 6 is requested for the reasons set forth below.

Claim 6 is dependent upon and dominated by allowed claim 1, but is further expressly limited to inclusion of "a member of a specific binding pair." It is stated that the specification only recites one specific biotin-avidin binding pair to which the antibody is coupled, and that this is not sufficient to satisfy the test of *Eli Lilly* and *University of Rochester.*

However, unlike the said two cases, specific binding pairs to which antibodies may be coupled are well known and long known. A few of the numerous patents which exemplify this group, in issued claims and long before the filing of the instant application, are US Patents Nos. 4,857,453 (*e.g.*, claim 18); 5,270,164; 5,437,983; 5,624,850; and 5,648,274.

Clearly this is the type of feature for which applicant should receive "credit for what is already known" in satisfying the written description requirement, a re-emerging theme in recent Federal Circuit decisions that has been emphasized by the USPTO. For the Examiner's convenient reference, Applicants provide herewith a copy of slides excerpted from a slide presentation presented at the USPTO in which one of the topics included the written description

requirement. *See attached Recent Biotech Case Law* presented by Stephen Walsh, Ph.D., J.D., Associate Solicitor, at the Biotech/Chem/Pharm Customer Partnership Meeting on November 10, 2005 (excerpt attached hereto).

Rejection under 35 U.S.C. § 112, second paragraph, indefinite.

Claims 2 and 21-24 stand rejected as indefinite. Claims 21-24 have been cancelled for the reasons noted above. Claim 2 has been amended in the manner helpfully suggested by the Examiner. Accordingly, it is respectfully submitted that this rejection may now be withdrawn.

It is respectfully submitted that this application is in condition for allowance, which action is respectfully requested.

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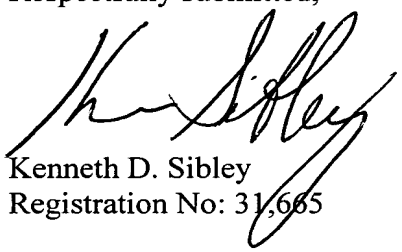
Respectfully submitted,



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Enclosure: S. Walsh slide presentation (excerpts)

Doc. 497868

RECENT BIOTECH CASE LAW

Stephen Walsh, Ph.D., J.D.
Associate Solicitor

Prepared for Biotech/Chem/Pharm Customer
Partnership Meeting, November 10, 2005

WRITTEN DESCRIPTION

Case law includes several tests for written description, including possession, but two themes are re-emerging in recent decisions.

Is the Federal Circuit's written description jurisprudence converging?

Themes Re-emerging In Recent Written Description Cases

- MPEP 2163 II.A.2:

  Inverse correlation between level of skill and knowledge in the art and the amount of description needed – what is already known does not have to be repeated in the specification
- MPEP 2163 II.A.3.ii:

  Predictability in genus/species cases – representative number inverse function of level of skill and knowledge in the art

First re-emergent theme: credit for what is already known

- *Capon v. Eshhar,* 418 F.3d 1349 (Fed. Cir. 2005)
  - old DNAs fused to make chimeric genes
- *Amgen v. Hoecsht Marion Rousell*, 314 F.3d 1313 (Fed. Cir. 2003)
  - mammalian and vertebrate cells
- *Union Oil Co. of Cal. v. Atlantic Richfield*, 208 F.3d 989 (Fed. Cir. 2000)
  - gasoline formulations
- *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570 (Fed. Cir. 1985)
  - food product

Capon v. Eshhar, 418 F.3d 1349 (Fed. Cir. 2005)

- Claims directed to chimeric genes to be made from known DNA sequences of known function using known procedures
- The Board found that "persons having ordinary skill would not have been able to visualize and recognize the identity of the claimed genetic material without considering additional knowledge in the art, performing additional experimentation, and testing to confirm results"

Capon (cont.)

The Court explained:

- "descriptive text needed . . . varies with the nature and scope of the invention at issue, and **with the scientific and technologic knowledge already in existence**"
- "as each field evolves, the balance also evolves between what is known and what is added by each inventive contribution"
- "Board's rule . . . is an inappropriate generalization"

A very old theme

Loom Co. v. Higgins, 105 U.S. 580, 586 (1881)

The inventor "may begin at the point where his invention begins, and describe what he has made that is new, and what it replaces of the old. **That which is common and well known is as if it were written out in the patent** and delineated in the drawings."